

1 UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY

3 CIVIL ACTION NUMBER:

4 IN RE: VALSARTAN PRODUCTS  
5 LIABILITY LITIGATION

19-md-02875

6 DISCOVERY CONFERENCE VIA  
ZOOM

7 Mitchell H. Cohen Building & U.S. Courthouse  
8 4th & Cooper Streets  
Camden, New Jersey 08101  
September 26, 2023  
9 Commencing at 4:02 p.m.

10  
11 B E F O R E: THE HONORABLE THOMAS I. VANASKIE (RET.)  
12 SPECIAL MASTER

13 A P P E A R A N C E S:

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25 Proceedings recorded by mechanical stenography; transcript  
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**A P P E A R A N C E S (Continued) :**

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**ALSO PRESENT:**

LORETTA SMITH, ESQUIRE  
Judicial Law Clerk to The Honorable Robert B. Kugler  
  
Larry MacStravic, Courtroom Deputy

1 (PROCEEDINGS held via Zoom before SPECIAL MASTER  
2 THOMAS I. VANASKIE at 4:02 p.m.)

3 SPECIAL MASTER VANASKIE: I have the agenda.

4 We'll get started and Loretta can join us. Maybe  
5 that's her coming in now.

6 I have your agenda letters. It seems to me there's  
7 not a whole lot to be addressed today, but I've been surprised  
8 before. And from what I understand, there are two topics to  
9 be addressed today. Maybe there's more.

10 But the first topic has to do with the end date for  
11 discovery from Aurobindo, at least as I understand it.

12 Do I have that right?

13 MS. GOLDENBERG: Hi, Your Honor. It's Marlene  
14 Goldenberg. More or less, yes. It's actually the end date  
15 just for a discrete number of custodians, but that's right.

16 SPECIAL MASTER VANASKIE: Right. Okay. And, Kate,  
17 you flashed on my screen, so are you addressing this on the  
18 defense side?

19 MS. DEAL: Yes, Your Honor. Good afternoon.

20 SPECIAL MASTER VANASKIE: Good afternoon. So where  
21 do we stand with this? Marlene, I'll ask you first.

22 MS. GOLDENBERG: Sure. So I'll start with the good  
23 news.

24 The good news is we agree on who the custodians  
25 should be. We agree on everybody who is going to end in 2019,

1 and we've agreed on five of the custodial productions going up  
2 through the present. So where that leaves us is with eight  
3 custodians in dispute. And the eight that are left are listed  
4 in our agenda letter, minus three of them. And I can read  
5 those names into the record if you want or --

6 SPECIAL MASTER VANASKIE: Why don't you. I have your  
7 letter, but why don't you read them in.

8 MS. GOLDENBERG: Sure. Maybe just for the sake of  
9 completeness.

10 The five that we've agreed that should go through the  
11 present are Sirinivas K. Rama. And that's not highlighted in  
12 our agenda letter. That's in the defendants', though.

13 The next one is Ram Mohan A. Rao. Then we have  
14 Sudhakar Reddy Mandepudi, Jaipal Reddy, and Blessy Johns.

15 SPECIAL MASTER VANASKIE: Okay.

16 MS. GOLDENBERG: All right. So now we get to the  
17 eight disputed custodians. And we've had lots of meet and  
18 confers and have just reached an impasse on these.

19 But again, you know, we agree on who the custodians  
20 are, we agree that these are relevant people, so really the  
21 only question is should these custodial productions go through  
22 the present.

23 And in order to answer that question, I wanted to  
24 give Your Honor a little context for what was happening at  
25 Aurobindo between 2019 and now so you kind of understand why

1 Aurobindo has this number being proposed.

2 So as a reminder, Aurobindo manufactured irbesartan  
3 at two different units, unit 1 and unit 9. And on June 20,  
4 2019, six months before Aurobindo wants to cut off the  
5 custodial productions for the eight custodians in dispute, the  
6 FDA sent Aurobindo a warning letter. And by the way, it was  
7 addressed to the first disputed custodia, Mr. Govindarajan.

8 I apologize if I didn't pronounce that correctly, but  
9 you'll see that he's the first one on our list.

10 And in the publicly available version of this letter,  
11 the FDA wrote that there were repeat observations at multiple  
12 sites, and they specific cite unit 1 and unit 9, again, where  
13 irbesartan was manufactured, as the facilities where they  
14 found repeat CGMP deficiencies. And they stated -- and I'm  
15 quoting now -- these facilities are also considered to be in  
16 an unacceptable state of compliance with regards to CGMP.  
17 These repeated failures at multiple sites demonstrate that  
18 management, oversight, and control over the manufacture of  
19 drugs are inadequate.

20 So after that, Aurobindo convened large teams of  
21 people to respond to this warning letter. And based on the  
22 documents that we have and what we can glean from the  
23 productions that have been made so far, the individuals on our  
24 list of disputed custodians were among the most important  
25 people who were involved in responding to this warning letter

1 and the 2019 warning letter that we're going to talk about in  
2 a minute.

3 So then we get to January 2022. And again, Aurobindo  
4 receives another warning letter, this one directed directly at  
5 unit 1 and again addressed to the same Mr. Govindarajan.

6 So this warning letter cited Aurobindo for a number  
7 of things, but most importantly it noted that Aurobindo failed  
8 to adequately inspect critical deviations and that it hadn't  
9 investigated things that had gone wrong very well.

10 So in other words, what went wrong with irbesartan is  
11 still being investigated, and the investigation continued long  
12 past the proposed December 2019 date for these custodians.

13 So I wanted to just point out one other thing. There  
14 is a response to this warning letter that was produced to us,  
15 and I didn't attach it to our agenda letter because it's more  
16 than 2,400 pages long. But to save you some time, the  
17 CliffsNotes version of this document is that Dr. Rao is  
18 responding to the FDA's warning letter, and he's writing to  
19 the FDA to tell the FDA all the things that Aurobindo has been  
20 doing to remedy these irbesartan issues. And not just remedy  
21 them, investigate them. So in other words, the investigation  
22 is still ongoing.

23 And just to give you a sample of how much they're  
24 still discussing irbesartan at this point in time, the word  
25 "irbesartan" appears in this document 1,791 times. The word

1 "nitrosamine" appears 742 times. So suffice it to say, this  
2 is still very much an ongoing investigation at Aurobindo  
3 during this time period. And because these ongoing  
4 investigations have continued, we've asked that these  
5 custodians be added to the list.

6 SPECIAL MASTER VANASKIE: All right. Thank you very  
7 much.

8 All right. Kate?

9 MS. DEAL: Good afternoon, Your Honor.

10 So as we get into some of the specifics and address  
11 some of the comments made by counsel, Your Honor, I just want  
12 to note at the outset that we don't raise a discovery dispute  
13 with the Court lightly. You haven't heard from us. And I  
14 think you can tell by our letter to the Court last week, we  
15 have been accommodating to the point of being conciliatory in  
16 irbesartan discovery negotiations with plaintiffs, probably to  
17 a fault.

18 The more we've given, the more plaintiffs have  
19 demanded. The goalposts keep moving out and expanding with  
20 each concession we make. So we're now in a position where we  
21 really believe that if these core concepts of relevance and  
22 proportionality that are in the rules actually apply, we've  
23 reached that point here.

24 And so, you know, to better understand that and the  
25 context in which this dispute arises, we really do need to

1 level set about the scope of plaintiffs' actual irbesartan  
2 claims against Aurobindo. By any measure, Your Honor, those  
3 claims are incredibly narrow, and the incredibly narrow scope  
4 of those claims dictates the appropriate scope of discovery  
5 under the rules.

6 As Your Honor may be aware, Aurobindo is not a  
7 defendant in losartan. That's not at issue. And there's no  
8 claims in this case against Aurobindo related to its finished  
9 dose irbesartan. Instead, the plaintiffs' economic claims  
10 here pertain to a very small quantity of Aurobindo's  
11 irbesartan API. And that API that forms the basis of their  
12 claims was manufactured using a particular process in 2016 and  
13 2017 and resulted in a recall in 2018 due to the alleged  
14 presence of NDEA. Aurobindo completed that recall in late  
15 2018.

16 To give you a sense of the scope here, the total  
17 dollar value of Aurobindo's net sales of the entirety of that  
18 recalled API is approximately \$200,000 in the aggregate.

19 With respect to personal injury claims against  
20 Aurobindo pertaining to that irbesartan API, there really  
21 aren't any, Your Honor. We've confirmed with plaintiffs' lead  
22 counsel that there appears to be only one single person in the  
23 entire MDL who claims any injury whatsoever from Aurobindo's  
24 irbesartan API that was recalled and that forms the basis of  
25 the claims in the MDL.



1           And so it's against this backdrop of this incredibly  
2 narrow scope of claims against Aurobindo in the irbesartan  
3 litigation that we have to evaluate the continually expanding  
4 requests for custodial discovery.

5           To date, Aurobindo has agreed to produce custodial  
6 data using very broad search terms for 22 custodians despite  
7 that narrow scope of claims across a six-year period, from  
8 2013 -- which, by the way, the plaintiffs expanded the start  
9 date of custodial discovery for irbesartan by a year from  
10 irbesartan core discovery. We thought that was not warranted,  
11 but we agreed to it. And we are agreeing to produce 22  
12 custodians' documents through December 2019, which extends a  
13 year past the completion of irbesartan -- of Aurobindo's  
14 irbesartan API recall that forms the basis of plaintiffs'  
15 claims. Just completing that custodial discovery, Your Honor,  
16 will exceed the total value of plaintiffs' pleaded claims  
17 against Aurobindo in the irbesartan MDL here.

18           As I mentioned -- as I may have mentioned, plaintiffs  
19 have already doubled the number of custodians we proposed.  
20 They extended the start date a year earlier than governed core  
21 discovery. They expanded the scope of the search terms that  
22 we tried to tailor to the actual claims here. And after all  
23 of that, Aurobindo agreed to custodial discovery for these 22  
24 custodians over a six-year period through 2019. And then  
25 after that, plaintiffs are now demanding four additional years

1 of custodial discovery from 13 custodians.

2 We think that's unjustified and improper for several  
3 reasons. First, it's inconsistent with their own document  
4 requests, which set an end date of December 2019. It's also  
5 inconsistent with the approach to custodial end dates taken in  
6 valsartan, where our custodial productions extended a year  
7 post recall, not five years post recall as plaintiffs now  
8 suggest is appropriate here. A year post recall is December  
9 2019 for Aurobindo in the irbesartan litigation.

10 Plaintiffs' latest proposal also disproportionately  
11 increases the existing collection and production of what is  
12 already terabytes of custodial data and millions of documents  
13 to be produced -- to review for production by an additional  
14 40 percent.

15 And all of this pertains to information that is  
16 largely untethered to plaintiffs' irbesartan-related claims to  
17 Aurobindo.

18 I want to point out, Your Honor, that plaintiffs'  
19 rationale for this multi-year expansion of custodial data is  
20 that they want to see internal communications about FDA  
21 communications that post-date Aurobindo's irbesartan API  
22 recall by up to five years.

23 But let me be super clear about this. Plaintiffs  
24 will already receive all of the FDA communications, everything  
25 FDA sends to Aurobindo and everything that Aurobindo sent

1 back, through May 22nd of 2023. And, by the way, they already  
2 have most of them. We produced all of that through September  
3 2022 when we made our core discovery productions.

4 Plaintiffs can make whatever arguments they wish to  
5 make about the contents of those documents. They know what  
6 the FDA inquired about after 2019, and they know the company's  
7 responses in full. As counsel just noted, we've produced  
8 thousands of pages about those regulatory inquiries. There is  
9 simply no basis for broad custodial discovery from Aurobindo  
10 into internal communications about regulatory communications.  
11 And, quite frankly, plaintiffs have never articulated one.

12 And it's certainly hard to do, because the additional  
13 custodial discovery they seek pertains to manufacturing from  
14 an entirely different time period than is at issue on the  
15 claims they pleaded here. It pertains to a different  
16 manufacturing process than those at issue here because that  
17 changed post recall. And perhaps most importantly, the  
18 additional communications about these regulatory  
19 communications don't involve any alleged nitrosamine  
20 impurities in Aurobindo's irbesartan API. The issues that are  
21 raised in the 2022 warning letter didn't result in API --  
22 didn't result in nitrosamine contamination. There is no claim  
23 in this case about that. It didn't happen.

24 So for all of these reasons, Your Honor, the latest  
25 request -- (technological interruption) -- by four additional

1 years, five years post-recall, in this incredibly broad  
2 fashion to us seems like a fishing expedition.

3           If plaintiffs have their way, we are embarking on a  
4 literal decade of vast custodial discovery from 2013 to 2023  
5 that all pertains to \$200,000 of irbesartan API sales that  
6 occurred in 2016 and 2017. That is disproportionate on its  
7 face and borders on absurd.

8           Nevertheless, Your Honor, given all of this, we don't  
9 think plaintiffs are entitled to any more custodial data. But  
10 we compromise. In yet another effort to meet them in a spirit  
11 of compromise, we offered five custodians, five additional  
12 custodians, for four additional years up to five years  
13 post-recall.

14           We explained to counsel their roles and why we  
15 thought they were the folks who had primary responsibility for  
16 any ongoing regulatory communications, because -- that  
17 plaintiffs already have. It includes the only US regulatory  
18 custodian on plaintiffs' list. It includes Dr. Rao, who was  
19 the primary person responding to the subsequent regulatory  
20 inquiries. It includes three other individuals who we think  
21 had the most robust involvement in these issues that we think  
22 have tangential relevance to the actual claims in this MDL.

23           So for all of these reasons, Judge Vanaskie, we think  
24 that what we've proposed is more than reasonable. It's  
25 certainly more than proportional in light of the narrow scope

1 of the claims here. And it's also reasonable and proportional  
2 given the already expansive custodial discovery we've agreed  
3 to, in light of the costs and the burden associated with it,  
4 in light of the fact that plaintiffs have all of the FDA  
5 communications back and forth through May of 2023, and in  
6 light of the fact that all of the regulatory issues identified  
7 by plaintiffs' counsel that pertain to 2016 through 2019 are  
8 already covered by the 22 custodians we've agreed to produce.

9 THE COURT: All right. Thank you.

10 Ms. Goldenberg, Marlene, do you want to address the  
11 proportionality concern that has been raised here?

12 MS. GOLDENBERG: Happy to, Your Honor. And I can do  
13 it in two points.

14 First of all, I'll say we disagree on the value of  
15 the case. We have economic class cases. We have a medical  
16 monitoring class, and the value of that, at least according to  
17 our internal calculations -- which I don't want to read into  
18 the record because I'm getting different numbers from people  
19 behind the scenes -- but I'll say that they are vastly  
20 different.

21 I can secondly say that this isn't really out of line  
22 in comparison to what other defendants have agreed to do. So,  
23 for example, ZHP has 80 custodians. You'll see that Vivimed  
24 has a number of custodians, and they agreed to bring everybody  
25 up a year past the production date, which is a pretty

1 comparative or comparable ask to what we're doing with half of  
2 the custodians that we agreed upon with Aurobindo.

3 And there are a lot of ongoing issues that Aurobindo  
4 has that other defendants don't. Other defendants either had  
5 factories close earlier, like Teva, or didn't have ongoing  
6 warning letters, and the other defendants who do have warning  
7 letters that have continued either are still negotiating or  
8 have agreed to produce more.

9 But in Aurobindo's case especially, they are being  
10 told directly by the FDA that their investigation isn't done.  
11 And, you know, we have a burden of proof at trial that we have  
12 to meet to show exactly what went wrong here. And if the FDA  
13 is telling Aurobindo you're not getting this right yet, then  
14 we have to be able to show that we have the documents that  
15 explain exactly what did go wrong. So, you know, there are  
16 lots of things still at play here that would justify these  
17 documents being produced.

18 SPECIAL MASTER VANASKIE: All right. Ms. Deal, would  
19 you address the question about the FDA findings and the  
20 indication that their investigation is not yet complete.

21 MS. DEAL: Yes, Your Honor.

22 So the FDA -- excuse me, 2022 letter from FDA is not  
23 about any irbesartan API that was manufactured in 2016 or 2017  
24 or that was recalled in 2018. It's different manufacturing,  
25 post-recall, using a different manufacturing process that

1 changed post-recall.

2           The letter identifies two issues. One is about the  
3 acceptable ammonia limit and whether the company needs to do  
4 additional testing to investigate the additional ammonia limit  
5 in a starting material that it had proposed, and the other  
6 deals with a process issue pertaining to method transfer.  
7 And, again, the FDA says, we need you to do more testing. But  
8 none of it pertains to the actual irbesartan API that was  
9 purchased by any claimant in this MDL, not at the same time  
10 period, not using the same manufacturing process. And, by the  
11 way, neither of those issues in the 2022 letter from FDA  
12 resulted in alleged nitrosamine contamination of any  
13 irbesartan API at any time, much less at the time period that  
14 governs the plaintiffs' claims here.

15           And so again, Your Honor, what's going on five years  
16 post-recall and seven years post-manufacture and sale of the  
17 API that forms the basis of plaintiffs' claims here is not  
18 tethered to what they need to prove in any trial. But,  
19 nevertheless, we've given all of them -- we've given them all  
20 of those regulatory documents, and they can say whatever it is  
21 they want to say about what happens five, six, seven years  
22 after the fact. But it doesn't pertain to the irbesartan API  
23 that their clients purchased or consumed, because it's  
24 different time periods, it's different manufacturing, and none  
25 of those subsequent issues related to a recall or any alleged

1 nitrosamine contamination in irbesartan API.

2 SPECIAL MASTER VANASKIE: Ms. Goldenberg, do you want  
3 to respond to that? I mean, I'm being told that this really  
4 doesn't deal with the product that's at issue here.

5 MS. GOLDENBERG: Yes, Your Honor.

6 So the document that I gave you the CliffsNotes from  
7 earlier -- and just for the record, the Bates number on that  
8 is APL-MDL-28752983378. Again, that's a February 3, 2022  
9 letter dated -- or sent from Aurobindo back to the FDA.  
10 That's the document that mentions or -- that mentions  
11 irbesartan over 1,700 times and that mentions nitrosamines, I  
12 think -- I don't have the figure in front of me, but  
13 hundreds -- 742 times again.

14 They're very much discussing their manufacturer and  
15 their investigation of the nitrosamine problem with the FDA in  
16 response to this letter.

17 Now, I do agree with Ms. Deal that the letter didn't  
18 call out irbesartan by name, but the response and the  
19 discussion that occurred with the FDA in response to that  
20 letter very much did.

21 And I should note too that the 2019 letter that we  
22 didn't hear Ms. Deal talk about is very much about irbesartan  
23 and the issues that occurred. And that went on long after  
24 December 2019 as well, especially with the FDA and Aurobindo  
25 both acknowledging that the problems in the 2022 letter were



1 similar to the CGMP issues that were addressed in the 2019  
2 letter.

3 SPECIAL MASTER VANASKIE: Is there -- go ahead,  
4 Ms. Deal, if you wanted to say something.

5 MS. DEAL: Yes. So just on that last point, Your  
6 Honor.

7 I just want everyone to remember that 2019 is within  
8 the time period we've agreed to. And so we are producing full  
9 custodial data for 22 custodians during that time period, and  
10 we also -- I think everyone reached an agreement with  
11 plaintiffs that if there is evidence that there is a  
12 discussion that is relevant, that is ongoing at the end of  
13 2019, plaintiffs can come back and request additional  
14 information to finish that thread. So that is already covered  
15 and agreed to.

16 What's at issue here is what's going on in 2022,  
17 which, again, as I've already explained, is truly, you know,  
18 more remote and untethered to the actual irbesartan API and  
19 the 2018 recall that is the basis of plaintiffs' pleading  
20 here.

21 And the other thing I just want to point out, Your  
22 Honor, is plaintiffs have all of that information. What  
23 they're asking for is custodial discovery for  
24 communications -- internal communications about those  
25 regulatory communications, which is even another step removed

1 from anything relevant here, when they have the full back and  
2 forth with the regulator. And so they're going to find some  
3 hidden gem in some internal communication that says, what  
4 about the irbesartan that was sold seven years earlier and  
5 recalled five years earlier. I mean, it truly is tangential.

6 And what we're agreeing to do in giving them all of  
7 the regulatory communications plus four additional years of  
8 custodial data for the five employees who have -- who we think  
9 have the most involvement in those activities is, you know, I  
10 think beyond generous and certainly beyond proportional to the  
11 needs of the case.

12 SPECIAL MASTER VANASKIE: Ms. Goldenberg.

13 MS. GOLDENBERG: Yes. One quick response on that,  
14 Your Honor.

15 You heard Ms. Deal mention that our deal was that if  
16 we found ongoing discussions that needed to be completed, we  
17 would raise them. And I suppose I could have waited until all  
18 of their documents poured in to do that, but why do that when  
19 I already know that they're incomplete now?

20 So, you know, all this is going to do if we go with  
21 Aurobindo's plan is kick the can down the road, and we're  
22 going to be back here right after they produce documents,  
23 saying, hey, Judge, they truncated their production in 2019.  
24 We know this warning letter went out six months before the  
25 custodial production ended. We're back because we don't have

1 it all and we knew we didn't have it all last time.

2 And the internal communications aren't something that  
3 we should brush aside as if they're not a big deal. These are  
4 all of the documents that are the building blocks to what goes  
5 out to the FDA, but we're going to get the internal test  
6 results. We're going to see where the deficiencies were,  
7 we're going to see the changes in the policies that showed how  
8 things slipped through the cracks before. These are the  
9 explanations for how this contamination happened.

10 And I haven't seen anybody try to argue that these  
11 aren't relevant in another context. This is just Aurobindo's  
12 attempt to say that we don't need it because it seems like  
13 they don't want to do the work to produce it. But this is  
14 very relevant at any time, including here.

15 MS. DEAL: Your Honor, believe me, we can be accused  
16 of a lot of things, but not doing enough work, given the  
17 claims that are leveled against our client, is truly not one  
18 of them, when we are offering 22 custodians for a six-year  
19 time period plus five additional custodians for an additional  
20 four-year time period to span an entire decade of custodial  
21 discovery about claims that amount -- that relate to our  
22 client's sale of \$200,000 worth of API in a one- to two-year  
23 period.

24 And so, again, they haven't articulated a reason why  
25 they need eight more, and, in fact, the reasons we got for the

1 additional eight I think I have factual errors and  
2 inconsistencies in them, and we've offered to confer about  
3 that them. But, again, the five people we're offering gives  
4 them everything that they're even asking for even if we think  
5 it is unreasonable.

6 And so -- and the other point I'll just respond to is  
7 we haven't done the custodial productions through 2019 because  
8 we're still spinning up backup tapes to pull out the six years  
9 worth of data that they're requesting for 22 people who in  
10 large part were not valsartan custodians. And so the notion  
11 that she's predicting the tea leaves that what we produced  
12 through 2019 is going to be deficient and warrant custodial  
13 data from 13 people through an additional four-year period is  
14 just made up. Right? It's not factually -- factually based  
15 in any production we've made or in anything that they've seen  
16 from any existing custodian to date.

17 SPECIAL MASTER VANASKIE: Why don't we proceed on  
18 that type of iterative basis, where you get the additional  
19 discovery from these five custodians up through May of 2023,  
20 see what is produced, and then if you have reason to believe  
21 that there's more, you come back.

22 Why is that not an appropriate approach?

23 MS. GOLDENBERG: We can do that, Your Honor, if  
24 that's your preference.

25 I would say that I do have specific reasons for why

1 we want each of these individuals, and there's nothing made up  
2 about our ask. I mean, I just read to you from a 2022 letter  
3 well outside of the time frame they're giving us documents for  
4 where they submitted 2,400 pages of material to the FDA on  
5 what they'd been doing since 2019.

6 But at a minimum, you know, I would think that we  
7 would get the regulatory affairs person over in India,  
8 Dasarathi, who's copied on pretty much -- at least in  
9 valsartan and my understanding is he had equal involvement  
10 with irbesartan, all of the regulatory issues. And then  
11 Mr. Govin -- oh, gosh. Govindarajan, who is the recipient of  
12 both FDA warning letters later on, we know for a fact that he  
13 was getting things beyond that point. And that falls directly  
14 in line with what Ms. Deal said that they should be producing  
15 to us anyway, which are all the regulatory documents.

16 MS. DEAL: Yes, Your Honor. They'll have all the  
17 regulatory documents. The question is, you know, what's a  
18 relevant and proportional number of custodial files to search  
19 given that they do have all of the regulatory responses.  
20 We've pitched the people who we think have the most primary  
21 responsibility there, and the hunch that somebody who was  
22 involved in valsartan must have been involved years later in a  
23 different drug with different issues is just not a valid  
24 assumption. And so, again, Your Honor, we're just picking  
25 names in a vacuum. And we're doing it without any regard to

1 burden or proportionality, because, again, what is happening  
2 in 2022 is not about the irbesartan that was manufactured and  
3 sold in 2016 and 2017 and recalled in 2018.

4 SPECIAL MASTER VANASKIE: It seems to me that at  
5 least the individuals that were just mentioned to me are not  
6 being pulled out of a hat or not selected at random, that  
7 there's a rational basis for suggesting that they're the kinds  
8 of persons or they have the kinds of positions that one would  
9 expect they would have relevant documents, relevant  
10 information. I'm talking about -- now about Mr. Govindarajan  
11 and the other -- I didn't get the name of the other person.

12 MS. DEAL: Yes. So, Your Honor, I think -- I mean,  
13 I'm going to butcher the names too.

14 I think the warning letters were sent to an  
15 individual, but he wasn't the one who signed the responses or  
16 sent the responses. We picked the people who were more  
17 substantively involved in that, because we assumed that that  
18 made more sense. We're happy to switch somebody out if that's  
19 what they want to do.

20 The other person, Dasarathi. This is an issue where  
21 I think plaintiffs have pulled him out based on a document  
22 they cite, but that document pertains to an entirely different  
23 production unit and pertains to an entirely different drug  
24 than what's going on with irbesartan at this time period.

25 SPECIAL MASTER VANASKIE: He's identified as the head

1 of regulatory affairs?

2 MS. DEAL: For corporate API, which is overseas. The  
3 reference that counsel gave to me, though, was a document  
4 where -- that relates to a different production unit  
5 altogether, unit 11. And it pertains to valsartan and not  
6 irbesartan.

7 And so our proposed custodians include the US head of  
8 regulatory affairs who is the person through whom all of the  
9 communications with the FDA go. And then we also produced  
10 the, you know, chief quality officer, Dr. Rao. He clearly is  
11 involved and is the one who signs all of the responses. And  
12 then we picked people at the relevant units who we thought had  
13 primary responsibility for the two issues that are in the 2022  
14 letter, plus a third custodian who appears to have more robust  
15 involvement.

16 If we want to trade some out because plaintiffs  
17 prefer others than those, I mean, we're happy to have that  
18 conversation, but we shouldn't just be adding people, you  
19 know, based on information that doesn't appear to be, you  
20 know, one, proportional, or, two, targeted to the custodial  
21 data that plaintiffs now claim is particularly relevant and  
22 that we dispute.

23 SPECIAL MASTER VANASKIE: It does appear to me that  
24 Mr. Govindarajan would be a person expected to have relevant  
25 information, not drawn out of a hat. And I would suggest that

1 he be added to the list of five persons, so now make it six,  
2 not to substitute him for another person.

3 And then Mr. Dasarathi, why would he be relevant,  
4 Ms. Goldenberg?

5 MS. GOLDENBERG: Your Honor, he is, as Ms. Deal said,  
6 the head of regulatory overseas. And I think perhaps she, you  
7 know, was splitting hairs a little bit when she said the one  
8 document that I was referring to in a previous email to her  
9 referred to unit 11.

10 My understanding from seeing lots of documents with  
11 his name on it is that he's copied on all of the regulatory  
12 issues that occurred over in India. And I'll tell you, I  
13 mean, I'm happy to go through them today. I've got reasons  
14 and documents cited for every single custodian we asked for.  
15 There are people on this list who were at the FDA closeout  
16 meetings for warning letters. There's a guy who greeted the  
17 FDA inspectors when they first showed up.

18 I mean, these are not random people. These are all  
19 people who are highly relevant to the FDA warning letter, not  
20 just in '22 but also in 2019, who -- you know, where that  
21 issue certainly went beyond the end of that calendar year.

22 MS. DEAL: Your Honor, I'll say, you know, the notion  
23 that somebody is copied on something, we don't need everybody  
24 who's copied on every email. Right? We don't need  
25 duplicative custodial discovery because, remember, what we're



1 talking about is pulling all of the custodial files for all of  
2 these people who end up as custodians for a four-year period  
3 using -- we had proposed tailored search terms. Plaintiffs  
4 rejected it. Using all of the search terms related to all  
5 irbesartan discovery issues that are in 26 pages and hundreds  
6 of different iterations.

7 And so adding people because they're copied on the  
8 same emails that the person we proposed actually sent and  
9 authored creates -- you know, it seems like it's not a big  
10 deal, but it does create an exponentially, you know, larger  
11 burden for no added benefit, because you're going to get those  
12 communications from the actual author of them.

13 MS. GOLDENBERG: I mean, I disagree with that  
14 characterization of who these custodians are. And, again,  
15 Your Honor, I mean, these are like the core people that were  
16 involved in these inspections. And I'm happy to either go  
17 through them today or submit additional materials on why these  
18 people are relevant, but I can assure you that they're all  
19 here for a reason.

20 SPECIAL MASTER VANASKIE: Well, I have no doubt about  
21 that, but I also know that you have to put some reasonable  
22 limits on discovery as well, even in a case of this magnitude.

23 I'm going to add two custodians to the five that are  
24 going to be searched. I'm going to add -- I'll butcher the  
25 names -- Mr. Govindarajan and Mr. -- I'm assuming it's a

1 Mr. -- Dasarathi. Add those two, conduct the search. You can  
2 come back later if you think now there are gaps or information  
3 has been produced that suggests that one of the other six -- I  
4 guess there will be six that you're not getting custodial  
5 files on through the May 2023 date. You can come back and  
6 make a showing that it's likely they would have relevant  
7 information, the production of which would be proportional to  
8 the needs of this case. And that's how we'll proceed. All  
9 right?

10 MS. GOLDENBERG: Understood. Thanks, Your Honor.

11 MS. DEAL: Thank you, Your Honor.

12 SPECIAL MASTER VANASKIE: All right. Next issue? We  
13 have an issue with respect to wholesaler discovery?

14 MR. STANOCH: Your Honor, this is David Stanoch for  
15 plaintiffs. I don't really think there's anything per se for  
16 an issue for Your Honor to decide today.

17 Our inserts on the retailers and wholesalers are  
18 really by way of updates since there's been so many moving  
19 parts and it's commanded so much of Your Honor's attention in  
20 the last few weeks. We just wanted to let you know where we  
21 are.

22 We noted a few things with wholesalers that were  
23 giving us a little concern, but, frankly, given all the moving  
24 parts, Judge, and where we are, I don't think there's anything  
25 for you to decide today. And if -- and we can come back, you

1 know, in two weeks if there's something. That would be my  
2 view.

3 SPECIAL MASTER VANASKIE: Yes. I thought -- my  
4 recollection is that you were proposing to address this at the  
5 October 4 conference.

6 MR. STANOCH: Potentially, yes, Judge. And I'm sure  
7 Mr. Geoppinger will speak for the wholesalers, but we received  
8 a proposed schedule from them yesterday evening, which we're  
9 still going through. And we're not immune to the reality,  
10 Your Honor, that even under their proposed schedule, some of  
11 this may shake out by a matter of eight days or so, it looks  
12 like. So I'm optimistic that even if we have a theoretical  
13 dispute, that it may not be worth everyone's effort, the  
14 parties and the Court, even for the next CMC, when it might  
15 shake out anyway in a matter of days from that date.

16 SPECIAL MASTER VANASKIE: Okay. Very well.

17 Is Mr. Geoppinger on the line? Did he want to --

18 MR. GEOPPINGER: Good afternoon, Your Honor, I am.  
19 And if there's nothing to argue about, I'm not going to  
20 volunteer to argue, so...

21 SPECIAL MASTER VANASKIE: Good. There's nothing to  
22 argue about.

23 Is there anything else for today?

24 Ms. Goldenberg, Ms. Deal, do you need anything more  
25 from me on this issue?

1 MS. GOLDENBERG: No, Your Honor. I think we've got  
2 our marching orders. Appreciate you calling balls and strikes  
3 for us today.

4 MS. DEAL: Thank you, Your Honor.

5 SPECIAL MASTER VANASKIE: Thank you very much. It  
6 was well presented.

7 Mr. Harkins, did you want to be heard on anything?

8 MR. HARKINS: No, Your Honor. Just noting no other  
9 issues I'm aware of for the defense.

10 SPECIAL MASTER VANASKIE: All right. Very well.  
11 Then we'll adjourn for today. And see you again soon.

12 Thank you all very much.

13 (Proceedings concluded at 4:40 p.m.)

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15

16 I certify that the foregoing is a correct transcript  
from the record of proceedings in the above-entitled matter.

17

18 /S/ Ann Marie Mitchell                      28th day of September, 2023  
Court Reporter/Transcriber                      Date

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